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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,128	04/09/2004	Jun E. Lee	IVGN 373	8246

65482 7590 08/21/2008

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
08/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,128	LEE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 32-82* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,6,8,9,15,55,59,62,64,65,71,76 and 78* is/are rejected.

7)☒ Claim(s) *15 and 71* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4,7,10-14,32-54,56-58,60,61,63,66-70,72-75,77 and 79-82.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 July 2008 has been entered.

Election/Restrictions

2. Claims 2, 4, 7, 10-14, 32-54, 56-58, 60, 61, 63, 66-70, 72-75, 77, and 79-82 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 30 August 2006.

Claim Objections

3. Claims 15 and 71 are objected to because of the following informalities: Claim 15 is multiply dependent. As presently worded, the aspect of it depending from "any of 1, 3, 5, 6, or 8-9" suggests that it could depend from both 8 and 9 at the same time. It is suggested that the claim refer to claims >>1, 3, 5, 6, 8, or 9<<.

4. Claim 71 depends from claims drawn to a non-elected invention.

5. Appropriate correction is required.

Claim Rejections - 35 USC § 101 & 112

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3, 5, 6, 8, 9, 55, 59, 62, 64, 65, 71, 76, and 78 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

9. As presently worded, the claimed composition fairly encompasses the template, which was elected by applicant to be mRNA; see claims 6, 8, 9, 62, 64, and 65. It is noted with particularity that not all nucleic acids have utility under 35 USC 101. An example of such are expressed sequence tags, or ESTs, for which no nucleic acids exists. Applicant's RNA template fairly encompasses just such an embodiment.

10. The claims do not distinguish between those nucleic acids that do and do not have utility under 35 USC 101 but rather, encompasses any and all manner of nucleic acids.

11. Applicant is urged to consider amending the claims such that the claims are drawn to those nucleic acids that unquestionably do have utility under 35 USC 101 and which are adequately supported by the original disclosure.

12. Claims 1, 3, 5, 6, 8, 9, 55, 59, 62, 64, 65, 71, 76, and 78 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a

specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to argument

13. At page 9, bridging to page 10 of the response of 24 July 2008, hereinafter the response, applicant's representative asserts "Applicants are not making a claim to a specific EST with an unknown target." This argument is not found to be persuasive as the claims encompass all ESTs, known and unknown.

14. While applicant's representative asserts that the claims are drawn to a composition, such does not avoid the issue of utility. The claimed composition must satisfy the utility requirement. Claim 8 specifically recites that the composition is to comprise an RNA template. The asserted utility for the composition is the analysis of the RNA template. A review of the disclosure and the response fails to find where applicant has asserted that the claimed and elected composition has any other utility.

15. While argument is presented that the claims may include both known and useful sequences as well as those that lack utility, the claims do not require that there be any useful nucleic acid template present. Applicant is urged to consider narrowing the scope of the claims to where the elected invention is fairly drawn to those embodiments that do satisfy the utility and enablement requirements.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,709,815 B1 (Dong et al.) in view of US Patent 6,906,244 B2 (Fischer et al.).

20. Dong et al., column 44, last paragraph, bridging to column 45, disclose a method by which PCR as well as RT-PCR is performed using mRNA as a template. Dong et al., also disclose that the reaction can be one that incorporates any combination of modified nucleotides.

The aspect of Dong et al., performing RT-PCR speaks directly to the presence of an enzyme with reverse transcriptase activity.

21. At page 11 of the response, applicant asserts that a review of Dong et al., at column 44, fails to indicate the use of both singular and plural uses of nucleotide analogs. As noted by applicants representative, Dong et al, at column 44, teaches in part:

> As used herein the term "nucleotide analog" when used in reference to targets present in a PCR mixture refers to the use of nucleotides other than dATP, dGTP, dCTP and dTTP; thus, the use of dUTP (a naturally occurring dNTP) in a PCR would comprise the use of a nucleotide analog in the PCR. A PCR product generated using dUTP, 7-deaza-dATP, 7-deaza-dGTP or any other nucleotide analog in the reaction mixture is the [therefore; *sic*] to contain nucleotide analogs.

22. Upon review of the cited passage, it is noted that Dong et al., refers to 'nucleotide analog,' which is in the singular sense, and states that this is to encompass "the use of nucleotide**s** other than dATP, dGTP, dCTP and dTTP" (Emphasis added.) Clearly, Dong et al., teach using nucleotide analogs, and that the PCR product is to "contain nucleotide analogs."

23. While Dong et al., has been found to disclose using various analogs, including dUTP, they have not been found to teach the use of aminoallyl-dUTP.

24. Fischer et al., column 49, fourth paragraph, discloses using aminoallyl-dUTP in an assay that utilized a reverse transcriptase and mRNA.

25. It is further noted that the reagents, including the aminoallyl-dUTP, were provided in a kit.

26. Attention is directed to the decision in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007):

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good

> reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

27. It is further noted that prior art is not limited to the four corners of the documentary prior art being applied. Prior art includes both the specialized understanding of one of ordinary skill in the art, and the common understanding of the layman. It includes "background knowledge possessed by a person having ordinary skill in the art. . . [A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR* at 1396.

28. Suggestion, teaching or motivation does not have to be explicit and "may be found in any number of sources, including common knowledge, the prior art as a while or the nature of the problem itself'" *Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007) citing *Dystar Textilfarben GMBH v. C. H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006).

29. For the above reasons, and in the absence of convincing evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Dong et al., by incorporating aminoallyl-dUTP into same, as disclosed by Fischer et al., as Fischer et al., teaches explicitly of using such to produce transcripts of mRNA and that such can also be provided in a kit.

30. In view of the detailed teachings, and advanced state of the art, said ordinary artisan would have had a most reasonable expectation of success.

31. Accordingly, and in the absence of convincing evidence to the contrary, claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76, and 78 remain rejected under 35 U.S.C. 103(a) as being

unpatentable over US Patent 6,709,815 B1 (Dong et al.) in view of US Patent 6,906,244 B2 (Fischer et al.).

Conclusion

32. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

33. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634